

REMARKS

Reconsideration of the subject application is requested in view of the above amendments and the following remarks. Claims 1 and 8 have been amended for purposes of clarity and to advance prosecution. The above amendments do not represent acquiescence to the Examiner's stated grounds for rejections and are made without prejudice to prosecution of any subject matter removed and/or modified by this amendment in a related divisional, continuation or continuation-in-part application. Following the amendments, claims 1-3, 8-12, 16 and 62 are pending in the application, with claims 1-3, 8-12 and 16 under active examination.

Claims 1-3, 8-12 and 16 stand rejected under 35 U.S.C. 112, first paragraph, as allegedly failing to comply with the written description requirement. According to the Examiner, one skilled in the art would not recognize from the present disclosure that Applicants were in possession of a genus of cell adhesion modulating agents that modulates cadherin-mediated cell adhesion and comprises an amino acid sequence of SEQ ID NO:1. The Examiner further states that the specification fails to provide sufficient descriptive information, such as definitive structural or functional features, or critical conserved regions.

Applicants respectfully traverse this rejection.

For purposes of clarity and to advance prosecution, Applicants have amended claim 1 such that the claimed modulating agents contain the amino acid sequence Asp/Glu-Trp-Val-Ile/Val/Met-Pro/Ala-Pro (SEQ ID NO:1); wherein Asp/Glu is an amino acid that is either Asp or Glu, Ile/Val/Met is an amino acid selected from the group consisting of Ile, Val and Met, and Pro/Ala is either Pro or Ala.

Applicants describe in the present application a new class of cell adhesion modulating agents based upon the identification of a novel cell adhesion recognition (CAR) sequence contained within classical cadherin cell adhesion proteins. The presently claimed consensus sequence contains six recited residues, three of which are invariant (positions 2, 3 and 6) and three of which permit only limited and clearly defined conservative substitutions (positions 1, 4 and 5). It is respectfully submitted that present disclosure is more than adequate to lead the skilled artisan to understand and appreciate that Applicants were in possession of this genus of compounds.

For example, as illustrated in Figure 2, the CAR sequence described by Applicants, and upon which the claimed consensus sequence is based, was identified from a small region of amino acid residues that is highly conserved across multiple cadherins (e.g., N-cadherin, P-cadherin, E-cadherin and R-cadherin) and across multiple species (e.g., human, mouse and cow). Further, as noted by the Examiner, and set forth in Example 2, Applicants have demonstrated that multiple representative species of the claimed genus of modulating agents indeed bind to the E-cadherin protein. Given that the ability of many CAR-based modulating agents to disrupt cell adhesion relies upon the disruption of intercellular protein-protein interactions at sites of contact where these interactions take place, there would be a reasonable expectation on the part of the skilled artisan that a peptide demonstrated to have the ability to bind to a classical cadherin protein at a defined CAR sequence would also possess some level of activity in disrupting cell adhesion mediated by the cadherin protein at that point of contact. In this respect, Applicants submit that Example 2 of the specification as filed establishes that multiple representative species possess activity relevant to the modulation of cadherin-mediated cell adhesion. Further still, Applicants have demonstrated that the representative species comprising the sequence DWVIPP was indeed effective for disruption of the cell adhesion properties of ovarian cancer cells, as expected based on its ability to bind E-cadherin in this important region.

All of the requirements necessary to satisfy the written description requirements under 35 U.S.C. 112, first paragraph, are submitted to have been more than adequately met by Applicants' disclosure. Applicants have disclosed a conserved core structure, SEQ ID NO:1. Applicants have disclosed relevant identifying characteristics that are coupled with this core structure and that are shared among members of the claimed genus, e.g., the ability to bind to classical cadherin proteins and disrupt cadherin-mediated cell adhesion. Further, Applicants have demonstrated relevant binding and/or modulating activity for multiple representative species encompassed by the claimed genus. Reconsideration is requested.

The Director is authorized to charge any additional fees due by way of this Amendment, or credit any overpayment, to our Deposit Account No. 19-1090.

Respectfully submitted,

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